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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,045	08/31/2001	Masahiro Sasaki	188-88	7829

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,045	SASAKI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27,29,30,35,36,39,49,51,54-56 and 60-62* is/are pending in the application.

4a) Of the above claim(s) *61, 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27, 29, 30, 35, 36, 39, and 49, 51, 54-56, and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 21-27, 29, 30, 35, 36, 39, and 49, 51, 54-56, and 60-62 are pending. The new claims 61 and 62 are different invention. The examined invention is a composition and the new claims 61 and 62 are drawn to method of using the examined composition. The inventions are distinct, each from the other because of the following reasons:

The examined inventions and the invention claimed in the new claims are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition as claimed could be used for inhibiting tyrosine kinase activity.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claims 61 and 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 21-27, 29, 30, 35, 36, 39, and 49, 51, 54-56, and 60 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification, maintained

The objection of the specification maintained because the "BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)" for Figures 1-4 comes after (i) DETAILED DESCRIPTION OF THE INVENTION.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112,

The rejection of claim 51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

Claim **49 remains rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is maintained, because of the limitation "of less than or equal to 100,000 daltons".

Applicant argues that the adequate support is in the specification as originally filed at page 9 that the molecular weight of the unhydrolized sericin protein is 100,000 daltons and the composition of the present invention may contain unhydrolized sericin protein, hydrolyzed sericin protein, which by definition must weight less than the unhydrolyzed protein, and mixtures thereof.

These arguments have been fully considered . However, the specification as originally filed has support for making sericin of an average molecular weight of either

100,000 (see the last sentence of Preparation Example 1 at page 9), or 20,000 (see the last sentence of Preparation Example 2 at page 9) with 90% purity or higher. The new limitation "of less than or equal to 100,000 daltons" are ranges from 1-100,000 daltons.

Claims 21-27, 29-30, 35-36, 39, and 49, 51, and 54-56 **remain rejected**, and new claim 60 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making sericin powder with molecular weight greater than 100 kDa with 90% purity or higher, does not reasonably provide enablement for making sericin powder with any other weight of less than 100,000 daltons. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant argues that the claims are amended to say "an average molecular weight of less or equal to 100,000 daltons", and hydrolyzed fragment of 100,000 daltons sericin would have an average molecular weight of less or equal to 100,000 daltons.

This argument has been fully considered but found unpersuasive because the base claim is drawn to a functional oral preparation with a purity of 90% or higher. It is not clear how one of skill could make a functional oral preparation at any one of an average molecular weight of less or equal to 100,000 daltons, for example 30,000 daltons with a purity 90% or higher.

Teramoto et al., (2005, Biosci. Biotechnol. Biochem., vol. 69, pages 845-847) at page 845, left column teach that three kinds of sericins exist: one greater than 250 kDa,

about 180 kDa, and about 100 kDa. Takasu et al., (2002, Biosci. Biotechnol. Biochem., vol. 66, pages 2715-2718) at page 2716 teach at Table 1 several different sizes of sericin, but none has molecular weight of 20,000. In addition, Takasu et al. teach at page 2715, right column, first full paragraph "no effective separations of sericins was established", at the time of the publication, which is 2002, two years after the effective filing date of the instant application.

Considering the unpredictable state of art, limited guidance in specification how to make the instantly claimed invention, it is concluded that undue experimentation to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

Claims 21-27, 29-31, 34, 36-39, 49-59 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. 6,165,982 (Yamada et al).

Claims 21-27, 29-31, 34, 36-39, 49-59 are drawn to composition suitable for oral administration comprising water-soluble sericin powder with a purity of 90% or higher (base claims 21) in an effective amount to prevent colon cancer in a dose form, wherein claim 22-26, 36, 38, and 39 list the effect, functional characteristics, and/or intended uses of the active ingredient of said sericin, wherein claim 27 lists an intended use i.e., "in the form of a health supplement", wherein claims 29 and 34 list the dose ranges of 1 mg to 1 g per kg per body weight, wherein claim 30 and 37 list the source of sericin, and claims 49 and 50 list the range of average molecular weight being 20,000 and 100,000, claims 54-59 list sericin of the base claims to be having about 1-5% by weight in the preparation.

Applicant argues that Yamada et al., do not teach mineral mixture. These arguments have been fully considered but found unpersuasive because aluminum sulfate (see column 4, line 66) is an important mineral according to "The Sulfates Class" downloaded from the url...http://www.galleries.com/minerals/sulfates/class.htm on 7/7/2006.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1642